510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant: Pega Medical Inc.
1111 Autoroute Chomedey
Laval, Quebec H7W 5J8
Canada

NOV 2 7 2013

Contact Person: Ariel R. Dujovne

Proprietary Name: The Free-Gliding SCFE Screw System

Common Name: SCFE screw

Device Classification: Class II

Classification Name: 21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener

Device Product Code: HWC

Establishment Registration Number: 9048931

Intended Use:
The Free-Gliding SCFE Screw System is indicated as a temporary implant for stabilization of pediatric femoral neck fractures and slipped capital femoral epiphysis (SCFE) in all pediatric patients (less than or equal to 21 years old) with the exclusion of newborn and infants under 2 years of age.

Description:
The Free Gliding SCFE Screw is a self-extending cannulated screw for use in fixation of slipped capital femoral epiphysis and femoral neck fractures. The design of the screw includes a male component (which is attached to the lateral cortex) and a female component (which is attached at the proximal epiphysis). Anchorage of the components is achieved through screw-type fixation. The screw has a built-in feature that allows for free extension of its length as the slipped capital physeal plate heals and normal patient growth continues. Stable fixation and rotational stability is created at the fracture (slip) site while avoiding compression forces thus avoiding premature closure of the physeal plate.

Basis for substantial equivalent:
The Free Gliding SCFE Screw System is claimed to be substantially equivalent in design and function to the following predicate devices:

1. Synthes 6.5 mm Cannulated Screw (Stainless Steel screws), Synthes USA. (K021932)

2. Hansson Pin System (Ti alloy nail and Stainless Steel screws & end caps), Howmedica Osteonics Corporation. (K964893 & K033968)

3. POGO Screw (Stainless Steel screws), FxDevices. (K092189 & K080649)

The intended uses of these devices are the same as the Free Gliding SCFE Screw System

Summary of Technologies:
The technological characteristics of the Free Gliding SCFE Screw System are equivalent or similar to those of the predicate devices.

Biomechanical Testing:
Static and Fatigue four-point bending tests, based on the ASTM F1264 "Standard Specifications and Test Method for Intramedullary Fixation Devices" were performed in order to establish safety and effectiveness of the Free-Gliding SCFE Screw System. These tests demonstrated comparable mechanical performances of the Free-Gliding SCFE Screw System to the predicate device tested in direct side by side testing. Moreover, engineering analysis of torsional strength and screw pullout strength further demonstrated strengths that exceed those of the predicate device with a significant margin of safety.

Clinical Testing:
No clinical testing is provided as a basis for substantial equivalence.

Conclusion:
Based on the similarities in the intended use, design, materials, manufacturing methods, and packaging, Free-Gliding SCFE Screw System has been established as substantially equivalent to the previously cleared predicate devices. Furthermore, mechanical test results demonstrate that the proposed Free-Gliding SCFE Screw System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 27, 2013

Pega Medical Incorporated
Ms. Ariel R. Dujovne
President
1111 Autoroute Chomedey
Laval Quebec H7W 5J8
Canada

Re: K131591
Trade/Device Name: The Free-Gliding SCFE Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: November 1, 2013
Received: November 4, 2013

Dear Ms. Dujovne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K131591

Device Name: **The Free-Gliding SCFE Screw System**

Indications for Use:

The Free-Gliding SCFE Screw System is indicated as a temporary implant for stabilization of pediatric femoral neck fractures and slipped capital femoral epiphysis (SCFE) in all pediatric patients (less than or equal to 21 years old) with the exclusion of newborn and infants under 2 years of age.

Prescription Use ____x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __no_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices